# 510(k) Summary

APR 2 4 2014

**Date Summary Prepared:** April 22, 2014

**510(k) Owner Information:** Defibtech, LLC
741 Boston Post Road
Guilford, CT 06437

**Contact Information:** Mr. Ed Horton
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**Trade (Proprietary) Name:** DDU-1000 Semiautomatic External Defibrillator and Accessories

**Common Name:** Semiautomatic External Defibrillator

**Classification Name:** Automated External Defibrillator (21 CFR 870.5310, Product Code MKJ)

**Predicate Device**

The DDU-1000 is a modification to the DDU-2300 predicate device. The design and intended use of the DDU-1000 AED is substantially equivalent in performance and safety to the DDU-2300 AED and accessories cleared under the following Proprietary Name:

| Proprietary Name | Manufacturer | 510(k) Number |
|---|---|---|
| DDU-2300 Semiautomatic External Defibrillator and Accessories | Defibtech, LLC | K081259 |

## Device Description

The DDU-1000 is a portable, Semiautomatic External Defibrillator (AED) intended for use on victims of sudden cardiac arrest (SCA). It is powered by a user-replaceable non-rechargeable battery pack and supports both adult and pediatric user-replaceable single-use defibrillation/monitoring pads.

The DDU-1000 employs a Patient Analysis System that ensures proper pad/patient connection and analyzes the patient's ECG rhythm to determine whether a shock is required. If needed, the DDU-1000 provides a 150 J (50J pediatric) impedance compensated, biphasic truncated exponential defibrillation shock to the patient without user intervention. The cardiac rhythm analysis algorithm and defibrillation energy and waveform utilized are the same as the predicate device.

Voice prompts provide simple instructions for the operator. The DDU-1000 AED is capable of recording event information including electrocardiogram (ECG), audio data and SHOCK/NO SHOCK recommendations.

## Intended Use

The DDU-1000 Semiautomatic External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:

- Unconscious and unresponsive
- Not breathing

For patients under 8 years old, or less than 55 pounds (25kg), use child/infant electrode pads. Do not delay therapy to determine exact age or weight.

The DDU-1000 AED must be used by or on the order of a physician.

## Comparison of Technology Characteristics

The DDU-1000 AED design characteristics are the same as those of the predicate device including the same battery and pads. Both devices employ the same underlying scientific technology for patient analysis and defibrillation therapy. Both user interface designs guide the user with voice prompts and visual guidance. The DDU-1000 AED user interface includes a simple stationary pictogram, which is illuminated with light emitting diodes (LEDs) to guide the user. In comparison, the user interface of the DDU-2300

AED (predicate device), which consists of a color liquid crystal display (LCD) screen that displays dynamic imagery and text prompts to guide the user through the event. In addition, the intended users are the same for both AEDs.

**Performance testing**

The DDU-1000 AED uses the same underlying technologies to provide functionally equivalent performance characteristics as the predicate device. Testing, including hardware verification, software validation, design validation and defibrillation waveform comparison, demonstrates that the DDU-1000 meets functional and/or performance specifications. Safety testing, including IEC 60601-2-4 for the "Particular Requirements for the Safety of Cardiac Defibrillators," IEC 60601-1-2 for "General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and Tests" and the ECG analysis and shock advisory system to the "American Heart Association's Automatic External Defibrillators for Public Access Defibrillation: Recommendation for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety," assures compliance with applicable industry safety standards.

**Conclusion Summary of Safety and Effectiveness**

Testing and performance evaluations demonstrate that the Defibtech DDU-1000 AED is substantially equivalent to the predicate device. The introduction of the DDU-1000 AED does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Defibtech, LLC
c/o Mr. Ed Horton
Vice President, Quality and Regulatory
741 Boston Post Road
Guilford, CT 06437

Re: K131525
Trade/Device Name: DDU-1000 Semiautomatic External Defibrillator and Accessories
Regulatory Number: 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: II (two)
Product Code: MKJ
Dated: March 11, 2014
Received: March 12, 2014

Dear Mr. Horton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131525

# Indications for Use

**510(k) Number (if known):** _____

**Device Name:** DDU-1000 Semiautomatic External Defibrillator and Accessories

**Indications For Use:**

The DDU-1000 Semiautomatic External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:

- Unconscious and unresponsive
- Not breathing

For patients under 8 years old, or less than 55 pounds (25kg), use child/infant electrode pads. Do not delay therapy to determine exact age or weight.

The DDU-1000 AED must be used by or on the order of a physician.

**Prescription Use** ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

FDA Date: 2014.04.24 07:38:46 -04'00'